REMARKS

In the Office Action dated October 6, 2004, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following 19 separate and distinct inventions:

Group I.	Claims 2-5 and 51-54, drawn to polynucleotide of SEQ ID NO:1 that encodes the polypeptide of SEQ ID NO:2, classified in class 536, subclass 23.4.
Group II.	Claims 6-9 and 55-58, drawn to polynucleotide of SEQ ID NO:3 that encodes the polypeptide of SEQ ID NO:4, classified in class 53, subclass 23.4.
Group III.	Claims 10-13, 18-20, 59-62, and 67-69, drawn to polynucleotides of SEQ ID NOS:5 and 9 that encode the polypeptide of SEQ ID NO:6, classified in class 536, subclass 23.4.
Group IV.	Claims 14-17 and 63-66, drawn to polynucleotide of SEQ ID NO:7 that encodes the polypeptide of SEQ ID NO:8, classified in class 536, subclass 23.4
Group V.	Claims 22-24, 35-36, 71-73, and 84-85, drawn to polypeptide of SEQ ID NO:2, classified in class 530, subclass 350.
Group VI.	Claims 25-27, 35-36, 74-76, and 84-85, drawn to polypeptide of SEQ ID NO:4, classified in class 530, subclass 350.
Group VII.	Claims 28-30, 34-36, 77-79, and 84-85, drawn to polypeptide of SEQ ID NO:6, classified in class 530, subclass 350.
Group VIII.	Claims 31-33, 35-36, and 80-85, drawn to polypeptide of SEQ ID NO:8, classified in class 530, subclass 350.
Group IX.	Claim 37, drawn to a method of modulating expression of B38, B55, and/or B60 with an effective amount of an agent, classification dependent upon agent structure.
Group X.	Claim 38, drawn to a method of modulating activity of B38, B55, and/or B60 with an effective amount of an agent, classification dependent upon agent structure.

Group XI. Claim 39, drawn to a method of treating a mammal by administering an agent that modulates the expression or activity of B38, B55, and/or B60, classification dependent upon agent structure.

Group XII. Claim 40, drawn to a method of treating a mammal by administering a protein, classified in class 514, subclass 2.

Group XIII. Claim 41, drawn to a pharmaceutical composition comprising B38, B55, and/or B60 or an agent capable of modulating B38, B55, and/or B60, classified in class 530, subclass 387.1.

Group XIV. Claim 42, 44-45, and 87-89, drawn to antibodies to a polypeptide, classified in class 530, subclass 387.1.

Group XV. Claim 43, drawn to an antibody to nucleic acid, classified in class 530, subclass 388.21.

Group XVI. Claim 46, drawn to a method of detecting B38, B5 and/or B60 in a biological sample using a protein-specific antibody, classified in class 435, subclass 7.21.

Group XVII. Claim 47, drawn to a method of detecting B38, B5 and/or B60 in a biological sample using a nucleic acid-specific antibody, classified in class 435, subclass 6.

Group XVIII. Claims 48-49, drawn to methods of diagnosing and monitoring a disease comprising screening for B38, B55 and/or B60 in a biological sample, classification dependent upon compound structure.

Group XIX. Claim 86, drawn to a method of treating a mammal comprising administering a nucleic acid, classified in class 514, subclass 44.

The Examiner acknowledges that Claims 1 and 50 links Groups I-IV and XIX; Claims 21 and 70 links Groups V-XVIII. The Examiner acknowledges that there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to different products or different methods. The Examiner contends that the restriction is proper because the products in Groups I, II, II, IV, V, VI, VII, VIII, XIII, XIV, XV, distinct from each other both physically and functionally, are not required one for the other,

and are therefore patentably distinct. The Examiner also contends that Groups IX, X, XI, XII, XVI, XVII, XVIII, and XIX are directed to methods that are distinct both physically and functionally, and are not required one for the other.

Specifically, the Examiner alleges that the products of Group I, IX, X, XI, XII, XVI, XVII, XVIII, or XIX can each be prepared by a process which is materially different from the process to prepare the product of anther Group, e.g., the polynucleotide of Groups I, II, III, IV, V, VI, VII, VIII, the pharmaceutical composition of Group XIII, the anti-polypeptide antibody of Group XIV, and the anti-polynucleotide antibody of Group XV.

The Examiner alleges that Group IX-XIX each requires certain search and consideration, which is not required by any of the other Groups.

The Examiner acknowledges that Groups I-IV and XIX; V-VIII and XII; XIV and XVI; and XV and XVII are related as product and process of use, respectively. However, the Examiner contends that the polynucleotides of Groups I-IV can be used in a materially different process from Group XIX, such as diagnostic or biochemical assays. Similarly, the Examiner alleges that the product of Groups V-VIII, XIV, and XV can be used in a materially different process of Group XII, XVI, and XVII, respectively.

The Examiner alleges that Groups I-IV and each of Groups IX, X, XI, XII, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. Similarly, the Examiner alleges that Groups V-VIII and each of Groups IX, X, XI, XVI, XVII, XVIII, and XIX are unrelated; Groups XIII and each of Groups IX, X, XI, XII, XVI, XVII, XVIII, and XIX are unrelated; Group XIV and each of Groups IX, X, XI, XII, XVII, and XIX are unrelated; Group XV and each of IX, X, XI, XII, XVI, XVIII, and XIX are unrelated.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect, with traverse, the subject matter of Group III, Claims 10-13, 18-20, 59-62, and 67-69, drawn to polynucleotides of SEQ ID NO: 5 and 9 that encode the polypeptide of SEQ ID NO: 6, for continued prosecution. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

Applicants respectfully submit that Groups I-XIX are clearly related to each other as different aspects of a single invention. The present invention identifies isolated nucleic acid molecules coding for proteins associated with modulation of obesity, diabetes and/or metabolic energy levels. For example, the nucleic acid or protein sequences of Groups I-VIII embody the same concept and represent different aspects of the present invention. The methods of Groups IX-XII employ the concept and products of Groups I-VIII. The pharmaceutical composition of Group XIII comprises the products and employs the concept of Groups I-VIII. The antibody of Group XIV reacts specifically to a polypeptide related to that of Groups I-IX. The antibody of

Group XV reacts specifically to a polynucleotide of Groups I-IV. Methods of Groups XVI-XIX employ the concept and products of Groups I-VIII and XIII. Hence, Groups I-XIX are clearly interrelated and interdependent.

Therefore, Applicants respectfully submit that Groups I-XIX are all different aspects of a single invention.

With respect to the sequence restriction, Applicants respectfully submit that even assuming *arguendo* that the claimed polynucleotide sequences are structurally distinct compounds for the purpose of the restriction requirement, the Examiner has erred in restricting the present application to elect only one or two sequences for further prosecution. In this connection, Applicants respectfully direct the Examiner's attention to MPEP § 803.04, which states:

> Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996).
>
> It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

MPEP § 803.04 (emphasis added). Thus, Applicants urge the Examiner to at least consider and examine Groups I-IV, which are directed to five nucleotide sequences, on the merits.

Applicants respectfully submit that the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as Applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

It is noted that Groups I-IV are classified in the same class and subclass. The Examiner's attention is respectfully directed to MPEP § 808.02, which states "where however, the classification is the same and the field of search is the same and there is no clear indication of separate future classified and field of search, no reasons exist for dividing among related inventions." In the present case, the classifications of the various groups overlap.[1] Notably, the class and subclass of Groups I-IV are identical. Additionally, there is no indication of separate future classification and field of search. Thus, in accordance with the MPEP, there is no reason for restricting among Groups I-IX, especially Groups I-IV.

[1] Groups V-VIII are also classified in the same class and subclasses. Groups XIII-XIV are classified in the same class and subclasses. Groups XIII-V are classified in the same class, which is the same as that Groups V-VIII are classified.

Moreover, reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than the growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, Applicants may be required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

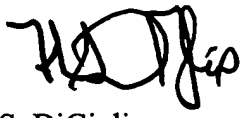
It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application, wherein various aspects in a unitary invention are claimed, or at least to consider Groups I-IV together.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined nineteen groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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